



THE UNITED STATES PATENT AND TRADEMARK OFFICE

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MAY 29 2002

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6-6-02

In re Application of: Eberhard Nieschlag et al.

Serial No.: 09/764,149

Group Art Unit: 1615

Filed: January 19, 2001

Examiner:  
Rachel M. Bennett

For: MALE CONTRACEPTIVE FORMULATION COMPRISING NORETHISTERONE

**SUPPLEMENTAL AMENDMENT**

Assistant Commissioner for Patents  
Washington, D. C. 20231

Sir:

Supplemental to the Amendment filed May 21, 2002, kindly amend the above-identified application as follows.

**IN THE SPECIFICATION**

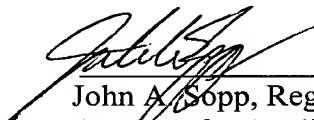
Replace page 20, in its entirety, with the attached new page 20. A marked up version is not supplied since no changes are made to the page, it is merely being replaced by a more legible copy.

**REMARKS**

A substitute, more legible, page 20 is being submitted per the Examiner's request in the Office Action of December 21, 2002.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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FILED: May 28, 2002

Table 1

## 1.1.1 Study flow chart

Visit	Screening		Start	Treatment										Observation			
	1	2		3	4	5	6	7	8	9	10	11	12	13	14	15	16
Assessment	A	B <sup>1</sup>	day 0 <sup>2</sup>	W2 <sup>3</sup>	W4	W6	W8	W12	W16	W18	W20	W24	W28	W36	W44	W56	
Group A																	
NET-EN administration (mg)			200			200		200		200							
TU administration (mg)				1000		1000		1000		1000							
Group B																	
NET-EN administration (mg)			400			400		400		400							
TU administration (mg)			1000			1000		1000		1000							
Group C																	
NET-A administration (mg)			10 mg														
Dispensation of vials			V 1/2														
TU administration (mg)			1000			1000		1000		1000							
Informed Consent/Demographics	ABC																
Check of Inclusion/Exclusion	ABC		ABC														
Randomization/Diary dispensed			ABC														
Medical/androl/medication history	ABC	ABC	ABC														
Vital signs	ABC	ABC															
Physical examination	ABC				ABC		ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC
Andrological examination	ABC				ABC		ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC
Semen analysis	ABC	ABC			ABC		ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC
General laboratory	ABC																
Hormones	ABC	ABC		A	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC
Exam/Ultrasonography of prostate		ABC															
Ultrasonography of testes		ABC															
Return of diary/vials, if available					C	C	C	C	C	C	C	C	C	C	C	C	C
AEs/concomitant medication				A	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC
Questionnaire	ABC	ABC			ABC		ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC

<sup>1</sup> At least 7 days after visit 1<sup>2</sup> Not more than 8 weeks after visit 1<sup>3</sup> A deviation of  $\pm 5$  days will be tolerated

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